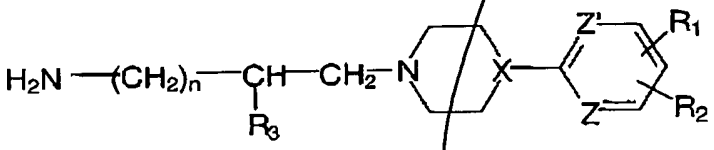
with a compound having the structure of Formula V in pyridine at reflux temperature followed by reflux in the presence of acetic anhydride



(V)

thereby to produce the compound of Formula I.

Remarks

In response to the Office Action dated July 3, 2001, Applicants have amended claim 44.

Rejection of Claim 44 Under §112

Claim 44 has been amended to include only pharmaceutically acceptable salts, enantiomers, diastereomers and N-oxides. Applicants believe that the present amendment removes the indefiniteness of claim 44.

Amendment of Claim 44

Claim 44 has been amended to include process parameters which find support in the examples of the application as filed.

Rejection of Claim 44 and 45 Under §102(b) and §103(a)

Applicants believe that claims 44 and 45 as presented herein are not anticipated by Ishizumi et al., Wu et al. or Khadilkar et al. Claim 44 as amended claims a process for the preparation of compounds which are different from the compounds disclosed in Ishizumi et al.,

Wu et al. or Khadilkar et al. The compounds of the present invention were specifically designed as highly selective and safe α_1-AR antagonists specifically for the use in BPH. The compounds of the present invention were found to possess α_1-AR antagonist selectivity which would then be used for treating BPH without causing vascular side effects, whereas no where do Ishizumi, et al., Wu et al. or Khadilkar et al. disclose or suggest α_1-AR selectivity.

The structural difference between the compounds of the present invention and Ishizumi et al., Wu et al., or Khadilkar et al. have been found to result in extremely high selectivity. Since the compounds of the present invention are novel and not anticipated by Ishizumi et al., Wu et al. or Khadilkar et al., therefore the process to prepare the novel compounds is also not anticipated. For this reason alone, the rejection of claim 44 should be reversed.

Applicants believe that claims 44 and 45 as presented herein are also unobvious over Ishizumi et al., Wu et al., or Khadilkar et al. As is well known, to establish a prima facie case of obviousness, three criteria must be met. First, there must be motivation in the prior art references to modify the reference. Second, there must be a reasonable expectation of success and third, the prior art reference must teach or suggest all the claimed limitations. In this connection, all the teachings and suggestions as well as the expectation of success must come from the prior art and not from the applicants' disclosure.

Reviewing the cited references, Ishizumi et al., Wu et al., Khadilkar et al., or New et al. there is no suggestion of the desirability for modifying the reactions to get the novel compounds for the selectivity as disclosed in the present invention. Further, it is clear that neither problem nor its solution is discernible to one with ordinary skill in the art from the teachings of prior art references. It is also known that the process parameters need to be optimized to suit the preparation of different compounds. Since the compounds of the present invention are novel, therefore, the process to prepare novel compounds is not obvious from the prior art.

It is, therefore, felt that a prima facie case of obviousness has not made and for this reason alone, the obviousness rejection should be overturned.

Conclusion

For the reasons stated above, the Examiner is urged to pass amended claim 44 and its dependent claim 45 to issue immediately. A clean copy of claims as amended is submitted herewith, and authorization is hereby given to charge any fees deemed to be due in connection with this Response to Office Action to Deposit Account No. 50-0912.

Respectfully submitted,

ANAND *et al.*

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Jayadeep R. Deshmukh, Esq.
Reg. No. 34,507

Date: January 2, 2002

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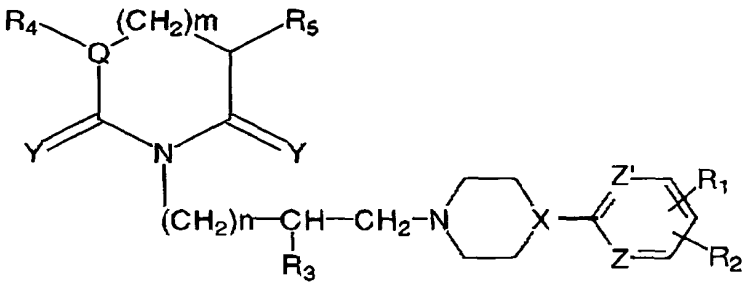
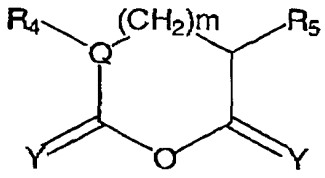
Clean copy of amended claim 44.

44. A method for making a compound having the structure of Formula I



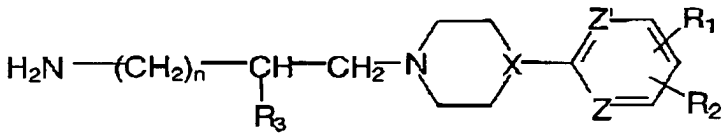
(I)

its pharmaceutically acceptable salts, enantiomers, diastereomers, or N-oxides, wherein Y is O or S; Q, Z and Z' are independently CH; X is CH or N; m=0-3; n=0-4; R_1, R_2 are independently selected from: H, F, Cl, Br, OCH_3, OC_2H_5, OCH_2CF_3, SCF_3, CH_3, C_2H_5, CF_3, isopropyloxy, and cyclopropyl; and R_5, R_4 and R_5 are independently H, C_{1-3} alkyl, substituted or unsubstituted phenyl, or a 5-membered spiro ring, except when R_1- R_5 are H; m is 0; n is 2; Q is CH; X is N; Y is O; Z and Z' are N, and except when R_1 is H; R_2 is H; Cl or CH_3; R_3- R_5 are H; m is 0; n is 1; X is N; Y is O; Z and Z' are CH, which comprises reacting a compound having the structure of Formula VI'



(VI')

with a compound having the structure of Formula V in pyridine at reflux temperature followed by reflux in the presence of acetic anhydride



(V)

thereby to produce the compound of Formula I.